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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D1105837 | (X3) Date Survey Completed 12/09/2019 |
| Name of Provider or Supplier Florida Digestive And Liver Specialist | Street Address, City, State 25 E Silver Palm Ave Ste B, Melbourne, FL | |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D0000 | A Recertification survey was conducted on December 9, 2019. Florida Digestive and Liver Specialists clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemical (IHC) stains at least twice annually from 7 /01/18 to 12/09/19. Findings: The laboratory used peer review to verify the accuracy of the reading and interpretation H&E stain, Special Stains and IHC stains. Review of the laboratory's records showed that there was no peer review of the Laboratory Director. The laboratory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), and H. pylori (Helicobacter pylori IHC stain). The laboratory evaluated the following special stains: Alcian Blue (mucopolysaccharides and glycoproteins stain), GMS (Gomori Methenamine-Silver stain for fungus), and PAS (Periodic Acid Schiff, polysaccharides stain). During an interview on 12/09/19 at 1:49 PM, the nurse stated she did not know where the peer review was located.</p> |
| D5601 | <p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other</p> |

differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to record the reactivity for Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemical (IHC) stains Findings: 1. Only the microscopic examination of the slides was performed at the laboratory. Review of the "Technical Quality Assurance Form and Slide Delivery" form used from 7/01/18 to 2/12/19 for patient #1 and #2, revealed there were no signatures for the "Histology: Quality Assurance Sign-off" indicating the H&E stain quality was acceptable. Review of the "Send Out Log Quality" form used from 2/13/19 to 12/09/19 for patients #5 and #6, showed there were no signatures in the "Reviewed" column or comments indicating the H&E stain quality was acceptable. During an interview on 12/9/19 at 4:45 PM, the nurse acknowledged that the acceptance of the stain quality was not indicated on the forms. 2. Review of the "Technical Quality Assurance Form and Slide Delivery" form showed that in the "Batch Control Slide Log" section there was no indication whether the Alcian Blue special stain was acceptable or rejected. Review of the "Send Out Log Quality" form for patients #4, showed there was no signature in the "Reviewed" column or comments indicating the GMS or PAS stain quality was acceptable. The laboratory evaluated the following special stains: Alcian Blue (mucopolysaccharides and glycoproteins stain), GMS (Gomori Methenamine-Silver stain for fungus), and PAS (Periodic Acid Schiff, polysaccharides stain). During an interview on 12/09/19 at 4:45 PM, the nurse acknowledged that the acceptance of the stain quality was not indicated on the forms. 3. Review of patient slides showed that there was no negative control slides for 3 out of 6 patient slides reviewed (#3, 5 & 6). Patient #3, #5, and #6 each had an IHC slide for H. pylori, and patient #6 had an IHC slide for CD3. The laboratory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), and H. pylori (Helicobacter pylori IHC stain). During an interview on 12/09/19 at 4:45 PM, the nurse acknowledged they did not have negative control slides for IHC stained slides.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory's pathology reports failed to provide the test results of the CD3 (Cluster of Differentiation 3 T cell Lymphocytic) Immunohistochemical (IHC) stain for 1 out of 6 patients' pathology reports examined, (#6). Findings: Review of the "Pathology Report" for patient #6

showed that there was no mention of the test results for the CD3 IHC stain. Observation of the slides for patient #6 showed that a CD3 stained slide was included with the other slides for the patient. During an interview on 12/09/19 at 4:45 PM, the nurse acknowledged that the test results of the CD3 stain were not mentioned on the pathology reports.